REMARKS/ARGUMENTS

Claims 1, 3, 6, 8, 22, 24-26, 34 and 35 are pending in the above-identified application. Claim 1 and 3 are amended as set forth in detail below. No new matter is added. In view of the remarks and amendments set forth herein, examination and reconsideration of all pending claims is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

"Administering locally"

Claims 3, 6, 8, and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, the Examiner contending that it is unclear what the meets and bounds of the term "locally" are as recited in the claim. This rejection is traversed in part and overcome in part as set forth below.

Essentially for reasons of record, Applicants again disagree with the Examiner's basis for the rejection. In particular, in addition to reasons previously stated in Applicants' amendment dated January 27, 2005, Applicants disagree with the Examiner's assertion that a clinician is not a person of ordinary skill in the art with respect to the pending method claims. Applicants note that, because administration of the Nr-CAM antisense nucleic acid would normally be carried out by a clinician, a clinician is indeed a person of ordinary skill in the art for purposes of determining definiteness under 35 U.S.C. § 112, second paragraph.

While Applicants disagree with the rejection, and without acquiescing thereto, Applicants have amended claim 3 to recite that the Nr-CAM nucleic acid is administered locally "at the site or former site of the tumor." Support for this amendment is found at, *e.g.*, page 85, line 24 through page 86, line 2, as previously discussed in Applicants' response filed January 27, 2005. This amendment is not believed to further limit the claim, but is recited to further define the term locally as would be understood by the skilled artisan reading the claim in light of the

specification. In view of this amendment, Applicants believe the rejection of claims 3, 6, 8, and 24 under 35 U.S.C. § 112, second paragraph, to be obviated.

"Effective amount"

Claims 3, 6, 8, and 24-26 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, the Examiner contending that it is unclear what the meets and bounds of the term "effective amount" are as recited in the claims. The Examiner asserts that there is a "lack of clarity regarding what amounts would be effective to accomplish what outcome" or "what the effective amount is supposed to accomplish."

While Applicants believe the term "effective amount" in claim 3 to be definite in light of the specification's disclosure and the claim's preamble, claim 3 has been amended to more explicitly set forth the effect to be achieved by reciting "wherein the Nr-CAM antisense nucleic acid is administered in an amount effective to inhibit tumorigenesis by inhibiting proliferation of a human tumor cell having high Nr-CAM expression." This language substantially corresponds to the language for "effective amount" in claim 1 (the pharmaceutical composition claim).

In view of this amendment, which sets forth with greater clarity what the effective amount is supposed to accomplish, Applicants believe the present rejection of claims 3, 6, 8, and 24-26 to be obviated. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102 or 35 U.S.C. § 103

Claims 1 and 22 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over, Lane *et al.* (of record). The Examiner contends that the recitation of "pharmaceutical" in claim 1 is a recited intended use that does not provide "much patentable weight" over Lane *et al.*, and that Lane *et al.* otherwise meets all of the structural limitations recited in the claims.

While Applicants do not agree with the Examiner for reasons of record, but in order to expedite prosecution of the instant application, claim 1 has been amended to recite, *inter alia*, "... wherein said composition is formulated for pharmaceutical use in humans." Support for this amendment is found throughout the specification as filed, including, for example, at page 88, lines 10-14 (stating that the pharmaceutical composition contains the therapeutic ingredient and carrier "so as to provide the proper form for administration to the patient" (emphasis provided)).

Claim 1 as amended explicitly requires, in the body of the claim, that the composition is formulated for pharmaceutical use. Therefore, Applicants submit that this limitation in not merely a recitation of intended use. Further, it is axiomatic that a composition formulated for pharmaceutical use must be physiologically compatible. As noted in Applicants' amendment filed January 27, 2005, the 1.1 kb nucleic acid disclosed in Lane *et al.* is a PCR product generated using synthetic PCR primers and which is used as a probe in Northern blotting solutions. (*See* Lane *et al.* at page 457, second column, last full paragraph). It is well-known that PCR solutions and Northern blotting solutions contain components that are not physiologically compatible (*e.g.*, formamide, SDS, and high salt concentrations such as disclosed in Lane *et al.* (*see id.*)). Accordingly, Lane *et al.* does not disclose a composition "formulated for pharmaceutical use in humans" as presently recited in the pending claims.

While Applicants do not agree with the Examiner's application of the 102/103 rejection to the pending claims, with respect to the Examiner's remarks that "a 35 U.S.C. 102(b)/103(a) combined rejection [] does not require [a showing of a] motivation," Applicants do agree with the Examiner insofar as the MPEP states that such a rejection is proper where the Examiner makes a *prima facie* showing that the compositions of the cited art and claims appear to be "identical or substantially identical." Applicants also note that such a rejection is successfully rebutted where the Applicants demonstrate that the composition disclosed in the cited art does "not necessarily possess the characteristics of the claimed product." MPEP § 2112.01 (emphasis original). In the present case, the nucleic acid composition of Lane *et al.* is not only "not necessarily" formulated for pharmaceutical use in humans, but, for the reasons set

forth above, Lane *et al.* expressly excludes such a characteristic by disclosing the 1.1 kb product only as a component in physiologically non-compatible Northern blotting solutions.

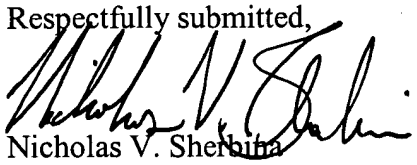
For the reasons set forth above, claim 1 as amended is novel and patentable over Lane *et al.* under 35 U.S.C. §§ 102 and 103. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,



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